

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

int(s)

Susan J. WONG et al.

10/699,550

Filing Date

October 31, 2003

Title

DIAGNOSTIC TEST FOR WEST NILE VIRUS

Examiner

Sharon L. Hurt

Art Unit

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DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

WE, SUSAN J. WONG AND PEI-YONG SHI, declare and state that:

- 1. We are the named inventors on the above captioned application (hereinafter "the present application") and are familiar with its prosecution history, including the Office Action mailed on February 22, 2006.
- 2. We, Susan J. Wong and Pei-Yong Shi, respectfully submit that we are experts in the field of serodiagnostic assays. Brief curricula vitae are attached as Appendices A and B. We have both been active researchers in this field for more than 6 years and, together and separately, have published more than 80 relevant primary articles in peer-reviewed journals and more than 8

review articles and contributions to books. We have obtained very substantial external research funding for our work in this area in open competition. We both lead research groups within Wadsworth Center in which we supervise more than 19 full-time research staff who are investigating aspects of diagnostic serology of human infections. We are both regularly asked to speak to the subject of serodiagnostic assays at national and international scientific meetings.

- 3. Accordingly, in view of our education, training and experience, we are considered by our peers to be experts in the field to which the present application pertains, and qualified to knowledgeably characterize the art to which the invention in the present application relates, and to speak as to the present application, and the invention claimed, including being qualified to present expert opinions about the present invention and literature in support of it, and documents cited against the present invention. Moreover, we respectfully submit that we are qualified to state the knowledge in the art, and that which would have been obvious and nonobvious to the skilled artisan.
- 4. It is our understanding that the Examiner rejected claims 74, 76-105, 126-128, 145, 156, and 162-202 under 35 U.S.C. §103(a) as being obvious over references Wang et al. ("Wang"), Valdes et al. ("Valdes"), Mandy et al. ("Mandy"), Scaramozzino et al. ("Scaramozzino"), and McDonell et al. ("McDonell").
- 5. More in particular, we were advised that in the February 22, 2006 Office Action, these claims were rejected because the Examiner believed that it would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teaching of Wang, Valdes and Mandy to use West Nile virus (WNV) recombinant nonstructural protein 5 (NS5) protein to detect WNV infections in humans and horses; that a person of ordinary skill in the art would have been motivated to use the NS5 and E proteins as immunodiagnostic assays for the detection of WNV in biological samples; that McDonell teaches a diagnostic kit with an immunogenic composition using ELISA and fluorescent labeling; and that one would have expected success because of the teachings of Scaramoizzino who developed a rapid, sensitive PCR assay for the detection of flavivirus with NS5 gene sequences.
- 6. The recombinant NS5-based microsphere immunoassay of the present application is an assay for detection of human or equine WNV infection that is useful for (i) differentiating between WNV infection and dengue (DEN) virus or St. Louis encephalitis (SLE) virus; (ii)

differentiating between flavivirus vaccination and natural WNV infection; and (iii) indicating recent WNV infections.

- 7. The assay of the present invention was initially disclosed in Wong, S.J. *et al.*, Immunoassay Targeting Nonstructural Protein 5 to Differentiate West Nile Virus Infection from Dengue and St. Louis Encephalitis Virus Infections and from Flavivirus Vaccination, Journal of Clinical Microbiology, Sept. 2003, p. 4217-4223 (hereinafter, "Wong *et al.*"). Wong *et al.* was cited on the Information Disclosure Statement, form PTO-1449, filed March 7, 2005. The Journal of Clinical Microbiology is a peer-reviewed journal.
- 8. The assay of the present invention is a highly sensitive diagnostic method for differentiating between flaviviral infections. This method works repeatedly.
- 9. Prior to the publication of Wong et al., such a highly sensitive method did not exist. This high sensitivity is due in part to the NS5 of WNV being covalently attached via its amino terminus to the surface of polystyrene microspheres. A suspension phase immunoassay using these microspheres is most specific for West Nile virus and only minimally cross reactive in sera from patients with other flavivirus infections. Moreover, the assay has a very low amount of non-specific reactions from other clinical conditions. In addition, until Wong et al., the use of the West Nile recombinant NS5 as a diagnostic target (antigen) had not been demonstrated for specific detection of West Nile antibodies or, indeed, for the specific detection of any flavivirus. Even today, most flavivirus assays are based upon killed virus, extracted from cell cultures or infected suckling mouse brain. Others are based on non-infectious viral particles comprised principally of the envelope protein that induces broadly cross-reactive sera.
- 10. At the time of filing of the present application, the state of the art did not teach or suggest to one of skill in the art that recombinant NS5 could be used with the Luminex platform to arrive at the present invention. The reviewers of the Wong *et al.* manuscript had the following comments:
 - REVIEWER 1: This paper provides data which may lead the way to the solution
 of a problem which has confounded and burdened the serologic diagnosis of
 flavivirus infection, e.g., cross reactivity.
 - REVIEWER 2: The manuscript by Wong *et al.* describes a serological test for WNV infection based on an E. coli-expressed form of NS5. In the assay format

- presented, this form of NS5 appears to be useful for distinguishing among infections with different flaviviruses.
- 11. The assay of the present invention has been shown by us to be useful for the detection of antibodies to WNV in the sera of vaccinated and naturally infected horses. This data was disclosed in Udeni, B.R. *et al.*, Detection Of Antibodies To West Nile Virus In Equine Sera Suing Microsphere Immunoassay, J. Vet. Diagn. Invest. 18:392-395 (2006). Table 2, (page 194, left column), shows that the NS5 microsphere immunoassay had 100% specificity in equine sera.
- 12. There exist various other technologies that could possibly be applied to use of NS5, however at the time of filing the present application none of these had been demonstrated to be effective strategies. Based on our knowledge and skill, we believed that there was a likelihood that assay strategies based upon passive adsorption to surfaces might not introduce the epitope of NS5 in a conformation and manner necessary for recognition of West Nile antibodies.
- 13. In November 2004, Focus Diagnostics investigated the use of the WNV recombinant NS5 antigen, provided by us, for use in an ELISA format for the detection of NS5 antibodies in serum panel from WNV patients. An indirect ELISA using NS5 coated plates was used to detect IgG, and an IgM capture format was used to detect IgM. The IgM capture ELISA used an anti-NS5 monoclonal antibody to detect NS5 antigen bound to IgM captured on the plate. The serum panel consisted of 110 sera previously characterized for the presence of antibodies to the WNV pre M/E recombinant protein. For the detection of IgG antibody, very weak reactivity was noted. Regardless of the NS5 coating concentration, no signal above an optical density (OD) (450nm) of 0.5 was found, and only 5 of 25 WNV IgG positive samples gave an OD between 0.3 and 0.5. All other samples in the serum panel had ODs less than 0.25. The detection of NS5 IgM positive samples was not possible with the reagents supplied. Accordingly, based on these results, of indirect IgG ELISA, the NS5 antigen did not show much reactivity with patient samples that were IgG positive on the Luminex platform. This low reactivity indicates that NS5 antigen coated onto plates could not discriminate true IgG positive samples from IgG negative samples. Furthermore, attempts to use NS5 antigen on IgM capture ELISA format was not successful since the monoclonal anti-NS5 antibody that was available for use did not show binding activity with NS5 antigen coated onto ELISA plates. The failure of other assays, it is clear, is due to the structure and properties of the NS5 protein rather than to human error.

- 14. Other than the luminex platform claimed in the present application, which work well repeatedly, there are no methods of rapidly diagnosing against WNV and discriminating West Nile virus from other flavivirus infections.
- 15. We further declare that statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signature: Sugan flog Date:	= 2/16/07
Susan J. WONG	<i>'</i> ,
Signature: Dayon Th. Date:	2/16/07

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CURRICULUM VITAE

Susan J. Wong

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CITIZEN:

USA and Canada

EDUCATION:

University of Saskatchewan	Biochemistry	Ph.D. 1980
University of New Hampshire	Biochemistry	M.Sc. 1972
University of Wisconsin	Molecular Biology	B.Sc. 1969

CERTIFICATION AND REGISTRATION:

Diplomate	American Board of Medical Laboratory Immunology	1985
(No.80)	Recertified	1998-2001
•	Recertified	2001-2004
	Recertified	2004-2007
RT	Canadian Society of Laboratory Technologists	1976
Certificate of	New York State Department of Health	2002 -2004
Qualification	(Diagnostic Immunology, Histocompatibility,	
	Bacteriology-Molecular Techniques)	

MEMBERSHIP:

American Society for Microbiology
American Society for Rickettsiology
American Society for Tropical Medicine and Hygiene
Infectious Diseases Society of America
International Conference on Diseases in Nature Communicable to Man (President 2004 – 2005)

HONORS AND AWARDS

1999	Wadsworth Center Recognition Award
2000	NYSDOH Commissioner's Recognition Award – West Nile Virus Response
2002	Charles Shepard Science Award Nominee from CDC, USPHS
2003	Thomas Nakano Commendation from CDC, USPHS
2004	NYSDOH Commissioner's Recognition Award – SARS Response

PROFESSIONAL AND RESEARCH EXPERIENCE:

Wadsworth Center New York State DOH Albany, New York	Research Scientist 6, Director Diagnostic Immunology, and Proficiency Testing (for DI and HIV)	Dec. 94 - Present
State University of New York at Albany	Assistant Professor Biomedical Sciences	Jan. 96 - Present
Regional Laboratory Red Deer Regional Hospital Centre Red Deer, Alberta, Canada	Clinical Specialist Immunology	1991 - 1994
Smith-Kline Beecham Clinical Laboratories Van Nuys, California	Manager, Immunology BioScience Laboratory	1991 (Mar to Aug)
Foothills Hospital Calgary, Alberta, Canada	Clinical Laboratory Immunologist	1988 - 1991
Foothills Hospital Calgary, Alberta, Canada	Laboratory Scientist Immunology	1982 - 1988
University of Calgary	Postdoctoral Fellow Medical Biochemistry	1980 - 1982
University of Liverpool United Kingdom	Postdoctoral Fellow Biochemistry	1980
University of Saskatchewan	Graduate Student Biochemistry Veterinary Physiology Dept.	1975 - 1980
	Technician (Research) Medicine and Pathology	1972 - 1975
University of New Hampshire	Graduate Student Biochemistry	1970 - 1972

Univ. of Rochester (NY) and Univ. of Minnesota (Mpls.)

Research Technician

1969 - 1970

Grants and External Funding (Current and Recent)

US Based Collaboration in Emerging Viral and Prion Diseases September '04 – September 05, (\$15,000/yr) Collaborator NIAID/NIH

Emerging Infections Program – Supplemental Surveillance of Human Granulocytic Ehrlichiosis. CDC/US PHS
Develop specific immunoassay for He and other tick-borne diseases
December '03 – December '04 (\$112,000/yr) PI

Enhanced Laboratory Capacity for West Nile Virus CDC Development of Diagnostic Assays for Human Infection by WNV. April '01 – April' 04 (\$100,000/yr) Dr. Dale Morse, PI.

Proposals Submitted (not funded)

Proposal Submitted (October 15, 2000). "Research on the Laboratory Diagnosis and Pathogenesis of Lyme Diseases in the United States" to CDC for Cooperative Agreement. Program Announcement 01-005.

Three SBIR proposals to NIH and DOD (from Inter Science Inc with subcontract to Wadsworth) for Miniaturization of Laboratory Systems ("Lab-on-a-Chip") submitted 1996, 1997.

Two SBIR proposals to NIH (with L Squared Diagnostics) on Tularemia (2002) and dengue fever (2004).

Contracts and Subcontracts Awarded

<u>Year</u>	Company	<u>Amount</u>	<u>Topic</u>
1997	Cambridge Diagnostics	\$2,076	Lyme Disease Assay
1999	Copalis Dia Sorin	\$7,973	Rubella Assay
2002	Abbott Laboratories	\$4,000	West Nile Assay
2002	NIAID	\$15,000	West Nile Assay
2003	Focus Technologies	\$17,500	West Nile Trial Site
2005	Spectral Diagnostics	\$13,095	West Nile Trial Site

Patents

United States Provisional Application 6/422, 755 filed October 31, 2002. (Susan J. Wong) "Diagnostic Test for West Nile Virus"

United States Provisional Application 454311-2260 Reference Number filed June 6, 2003. (Susan J. Wong and Pei Yong Shi). "Diagnostic Test for West Nile Virus.

Recent Workshop and Meeting Participation (2004-2006)

- 2006 American Society of Retina Specialists, September 7-14, 2006. Cannes France.
- 2006 International Conference on Disease in Nature Communicable to Man. August 6-9, 2006. San Antonio, TX.
- 2006 National West Nile Virus Conference. February 22-24, 2006. San Francisco, CA.
- 2005 American Society of Tropical Medicine & Hygiene. December 11-14, 2005. Washington, DC.
- 2005 60th Annual International Conference on Diseases in Nature Communicable to Man. August 7-9, 2005, Calgary, Alberta, Canada.
- 2005 American Society of Microbiology Eastern New York Branch. New technologies in microbiology. March 7, 2005, Albany Medical Center, Albany, NY.
- 2005 West Nile Virus Review and planning meeting (Public Health Agency of Canada). Jan 10-11, 2005. Ottawa, Ontario, Canada.
- 2005 National Conference on West Nile Virus in the United States. Feb 8-9, 2005. San Jose, CA.

PAPERS PUBLISHED (Also under S.J. Johnson, S.J. Bagley)

- 1. Gardner, I.A, S.J. Wong, G.L. Ferraro, U.B. Balasuriya, P.J. Hullinger, W.D. Wilson, P.Y. Shi, N.J. MacLachlan. Incidence and Effects of West Nile Virus Infection in Vaccinated and Unvaccinated Horses in California. Vet. Res. 38 (2007) 109-116.
- 2. Beer, P.M, S.J. Wong, A.M. Hammad, N.S. Falk, M.R. O'Malley. Vitreous Levels Of Unbound Bevacizumab And Unbound Vascular Endothelial Growth Factor In Two Patients. Retina. 2006. 26:871-876.
- 3. Balasuriya, U.B., P.Y. Shi, S.J. Wong, V.L. Demarest, I.A. Gardner, P.J. Hullinger, G.L. Ferraro, J.D. Boone C.L. De Cino, A.L. Glaser, R.W. Renshaw, M. Ledizet, R.A. Koski, and N.J. MacLachlan. Detection of antibodies to West Nile virus in equine sera using microsphere immunoassay. J Vet Diagn Invest. 2006 July 18 (4): 392-5.
- 4. Nguyen, Q., S. Teran, J. Snedeker, C.B. Morrow, C. Huang, W. Wong, B. Wallace, L.F. Novick. CNS Sequelae in an Infant with Congenital West Nile Virus Infection. Infections in Medicine. Dec. 2005. pp. 626-628.
- 5. O'Connor, K. C., H. Appel, L. Bregoli, M.E. Call, I. Catz, J.A. Chan, N.H. Moore, K.G. Warren, S.J. Wong, D.A. Hafler, and K.W. Wucherpfennig. 2005. Antibodies from Inflamed Central Nervous System Tissue recognize Myelin Oligodendrocyte Glycoprotein.. Journal of Immunology. 175: 1974-1982.

- 6. De la Fuente, J., R.F. Massung, S.J. Wong, F.K. Chu, H. Lutz, M. Meli, F.D. von Loewenich, A. Grzeszczuk, A. Torina, S. Caracappa, A.J. Mangold, V. Naranjo, S. Stuen, and K.M. Kocan. Sequence Analysis of the msp4 Gene of Anaplasma phagocytophila Strains. 2005. Journal of Clinical Microbiology 43:1309-1317.
- 7. Kumar, D., M.A. Drebot, S.J. Wong, G. Lim, H. Artsob, P. Buck, and A. Humar. 2004. A Seroprevalence Study of West Nile Virus Infection in Solid Organ Transplant Recipients. Am J. Transplantation. 4:1296-1301.
- 8. Wong, S.J., V.L. Demarest, R.H. Boyle, T. Wang, M. Ledizet, K. Kar, L.D. Kramer, E. Fikrig, and R.A. Koski. 2004. Detection of Human Anti-Flavivirus Antibodies with a West Nile Virus Recombinant Antigen Microsphere Immunoassay. J. Clin. Microbiol. 42:65-72.
- 9. Shi, P.-Y. and Wong, S.J. 2003. Serologic Diagnosis of West Nile virus infection. Expert Rev. Mol. Diagn. 3(6):89-97.
- Wong, S.J., R. H. Boyle, V. L. Demarest, A. N. Woodmansee, L.D. Kramer, H. Li, M. Drebot, R. A. Koski, E. Fikrig, D. A. Martin, and P.-Y. Shi. 2003. Immunoassay Targeting Nonstructural Protein 5 to Differentiate West Nile Virus Infection from Dengue and St. Louis Encephalitis Virus Infections and from Flavivirus Vaccination. J. Clin. Microbiol. 41:4217-4223.
- 11. Barbet, A.F., P.F.M. Meus, M. Belanger, M.V. Bowie, J. Yi, A.M. Lundgren, A.R. Alleman, S.J. Wong, F.K. Chu, U.G. Munderloh, and S.D. Jauron. 2003. Expression of Multiple Outer Membrane Protein Sequence Variants from a Single Genomic locus of *Anaplasma phagocytophilum*. Infect. Immun. 71:1706-1718.
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- 13. Wang, T. L.A. Magnarelli, J.F. Anderson, L.H. Gould, S.L. Buschmich, S.J. Wong and E. Fikrig. 2002. A Recombinant Envelope Protein-Based Enzyme-Linked Immuno-Sorbent Assay for West Nile Virus Serodiagnosis. Vector Borne and Zoonotic Dis. 2:105-109.
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- 19. Wong SJ and SJ Seligman. 2001. Long Term Stability of West Nile Virus IgM and IgG Antibodies in Diluted Sera Stored at 4 C. Ann NY Acad. Sciences. 951: 369-372.
- 20. Kulas K, V Demarest, and SJ Wong. 2001. Use of an Arboviral Immunofluorescent Assay in Screening for West Nile Virus. Ann. NY Acad. Sciences 951: 357-360.
- 21. Alleman, A.R., A.F. Barbet, M.V. Bowie, H.L. Sorenson, S.J. Wong and M. Belanger. 2000. Expression of a Gene Encoding the Major Antigenic Protein 2 Homolog of *Ehrlichia chaffeensis* and Potential Application for Serodiagnosis. J. Clin. Micro. 38: 3705-3709.
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- 23. Linden, J.V., S.J. Wong, F.K. Chu, G.B. Schmidt and C. Bianco. 2000. Transfusion-associated transmission of babesiosis. Transfusion 40:285-289.
- 24. CDC (S. Wong, "reporter"). 1999. Update: West Nile Virus. Encephalitis-New York, 1999. MMWR. 48:944-946, 955.
- 25. CDC (S. Wong, "reporter"). 1999. Update: West Nile-Like Viral Encephalitis-New York, 1999. MMWR 48:890-892.
- 26. CDC (S. Wong, "reporter"). 1999. Outbreak of West Nile-Like Viral Encephalitis-New York, 1999. MMWR 48: 845-849.
- Wong, S.J., and J.A. Thomas. 1998. Cytoplasmic, Nuclear, and Platelet Autoantibodies in Human Granulocytic Ehrlichiosis Patients. J. Clin Microbiol 36: 1959-1963.
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- Wong, S.J., G.S. Brady, and J.S. Dumler. 1997. Serological Responses to *Ehrlichia equi*, *Ehrlichia chaffeensis*, and *Borrelia burgdorferi* in New York State. J. Clin Microbiol 35: 2198-2205.
- 33. Ramani, R., A. Ramani, and S.J. Wong. 1997. Rapid Flow Cytometric Susceptibility Testing of *Candida albicans*. J. Clin. Microbiol 35: 2320-2324.
- 34. CDC (S. Wong "reporter") Human Granulocytic Ehrlichiosis New York, 1995. MMWR 1995. 44:593-595.
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- 37. Johnson, S.J., Gupta, V.S., Stevenson, K.J., and Frieisheim, J.H., Purification and characterization of dihydrofolate reductase from Walker 256 carcinosarcoma. Can. J. Biochem., 60, 1132-1142 (1982).
- 38. Sargent, A.U., and Johnson, S.J. The hemolytic equivalence of human, guinea pig, and canine complement components. Immunological communications, 9, 453-463 (1980).
- 39. Johnson, S.J., Metcalf, E.C., and Dean, P.D.G. The determination of dissociation constants by affinity electrophoresis on cibacron Blue F3G-A agarose-polyacrylamide gels. Anal. Biochem., 109, 63-66 (1980).
- 40. Johnson, S.J., Stevenson, K.J. and Gupta, V.S. Procion dyes as affinity ligands and reporter groups for dihydrofolate reductase from Walker 256 carcinosarcoma. Can. J. Biochem., 58, 1252-1257 (1980).
- 41. Sargent, A.U., S.J. Johnson and A.K. Richardson. Isolation and functional purification of the first seven components of canine hemolytic complement. Immunochemistry 13 (10), 823-829 (1976).
- 42. Zigman, S. and S.J. Bagley*. Near ultraviolet effects on dogfish retinal rods. Exp. Eye Res., 12, 155-157 (1971).

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ABSTRACTS

- 1. Wong, S.J., P.M. Beer. Suspension Phase Microsphere Immunoassay of Bevacizumab Levels in Ocular Fluids and Sera. American Society of Retinal Specialists, Cannes France. September 7-14, 2006.
- 2. Wong, S.J., L.D. Kramer, G.D. Ebel. Powassan Encephalitis. International Conference on Diseases in Nature Communicable to Man. International Conference on Diseases in Nature Communicable to Man. San Antonio, TX. August 6-9, 2006.
- 3. Wong, S.J., U.B. Balasuriya, P-Y Shi, I.A. Gardner, P.J. Hullinger, G.L. Ferarro, J.D. Boone, C.L. DeCino, V.L. Demarest, A.L. Glaser, R.W. Renshaw, M. Ledizet, R.A. Koski, N.J. MacLachlan. Equine Antibody Responses to West Nile Virus Infection and Vaccination: Multiplex Microsphere Immunoassay with structural and Nonstructural Viral Proteins Compared to Plaque Reduction Neutralization. Annual West Nile Virus Conference. San Francisco, CA. February 22-24, 2006.
- 4. Campbell, M.M., S.J. Wong, E. Bell, S. Gohel, J. Paley, E. DeBernardo, A. Fine. False Positive West Nile IgM ELISA Tests in Outpatients with Febrile Illnesses, New York City, 2005. Annual West Nile Virus Conference. San Francisco, CA. February 22-24, 2006.
- 5. Wong, S.J., A.P. Dupuis II, A.M. Kilpatrick, P.P. Marra, A.L. Glaser, T. Victor, P. Daszak, L.D. Kramer. Comparison of Indirect ELISA and Plaque Reduction Neutralization to Multiplex Microsphere Immunoassay for Detection of Antibodies to West Nile Virus in Blood of Wild Birds. American Society for Tropical Medicine & Hygiene. 54th Annual Meeting, Washington, DC. December 11-14, 2005.
- 6. Wong, S.J., F. Chu, K. Kulas, J. S. Dumler, L. Berrada, S. Hennigan, D. Katz, B. Matyas, D. Pereira, S. Soliva, V. Berardi, K. Weeks, E. Fikrig. Laboratory Investigation of Human Granulocytic Anaplasmosis in the Housatonic River, River Valley, Berkshire County, Massachusetts 2004. International Conference on Diseases in Nature Communicable to Man, Calgary, Alberta, Canada. August 7-9, 2005.
- 7. Wong, S.J., M. Behr, F. Chu, V. Demarest, E. Fikrig, N. Ramamoothi, Y.-F. Chang, D. Lawrence. Multiplex Microsphere Immunoassay (MIA) for the Detection of Antibodies to Recombinant Proteins Derived from *Borrelia burgdorferi* and *Lxodes scapularis* Saliva in Retrievers with Lyme Borreliosis Associated Glomerulonephritis (GN). International Conference on Diseases in Nature communicable to Man. Calgary, Alberta, Canada. August 7-9, 2005.

- 8. Strik, N.I., A.R. Aleman, A. Barbet, H. Sorenson, F.P. Gaschen, N. Luckschander, S. J. Wong, F. K. Chu, A. Bjoersdorff, S. Stuen. Cross-reactivity of Major Surface Protein 5 of *Anaplasma phagocytophilum* and *Anaplasma marginale* and its Significance for Diagnostic Use. American College of Veterinary Pathology. Boston, MA. December 2005.
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- Toshinobu Mizuta, Masakazu Adachi, Takashi Kosedo, Katsuuki Nakajima, Kunikazu Akutsu, J.A. Williamson, Nobuhito Kashiwagi, Mamoru Ohnishi, Chiaki Shiozawa, Taiki Tamaoki, M.J. Gill, T. Bowen, M.-C. Poon, D.S. Matheson, S. Johnson1, D. Church, Kazuko Handa, Sen-Ichiro Hakomori, Yoshihiro Ohta, Masanori Hayami. Expression of Carbohydrate Antigen on HIV Infected Cells. III. The expression of Ley antigen and the change of host cells. 1st AIDS Research Meeting in Japan. Kyoto Calkin, Univ. of Kyoto, Kyoto, Japan. December 21-22, 1987.
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2. http://www.cdc.gov/ncidod/dvbid/westnile/conf/march_2002.htm. West Nile Virus Serology MRL IFA versus ELISA and New Technologies. Breakout Session 2, Lab Diagnosis.

Biomedical Sciences SUNYA School of Public Health

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- 1. Lectures in three courses annually (Introductory Immunology, Biological Basis of Public Health, Epidemiology of Infectious Diseases) with a total of about 6 lectures given.
- 2. Current member of the Admissions Committee for professional programs (MPH, DrPH) at SPH. Past member of the Personnel Committee.
- 3. Previous mentor for SUNYA undergraduate research projects, REU students, CDCEIP fellows.
- 4. Previous host/mentor for visiting scientists from Taiwan, Canada, Maine, Pennsylvania. Florida, Washington and other locales.

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BIOGRAPHICAL SKETCH

ide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

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istant Professor

THE STATE OF THE S	POSITION TITLE
Shi, Pei-Yong	Research Scientist/Assi

eRA COMMONS USER NAME

Pei_Yong_Shi

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

Nanjing Normal University, China	DC		
	B.S.	1989	Biochemistry
Georgia State University, Atlanta, GA	Ph.D.	1995	Molecular Virology
Yale University School of Medicine, New Haven, CT	Postdoc.	1998	Biochemistry

A. Positions and Honors

Positions and Employment

1992-1995	Research Assistant, Ph.D. program in molecular virology, Department of Biology,
	Georgia State University, Atlanta, GA.
1996-1998	Postdoctoral associate, Department of Molecular Biophysics and Biochemistry,
	Yale University School of Medicine, New Haven, CT.
1998-2000	Principal Investigator, Department of Anti-infectious Diseases,
	Bristol-Myers Squibb Pharmaceutical Research Institute, Wallingford, CT.
2000-	Research Scientist, Division of Infectious Diseases,
	Wadsworth Center, New York State Department of Health, Albany, NY.
2001-	Assistant Professor (2001-2005), Associate Professor (2006-), Department of Biomedical
	Sciences, School of Public Health, State University of New York-Albany, NY.

Other Experience and Profession Services

O 11101	TO THE CONTRACT OF THE CONTRAC
2003-	Reviewer for Journal of Virology, Virology, Journal of General Virology, and Journal of Clinical
	Microbiology
2003-2004	Ad Hoc reviewer, NIH Special Study Section on Bioterrorism and Emerging Infectious Diseases
2004	Member, NIH Bioshield Study Section
2004	Ad Hoc reviewer for grants sponsored by US Civilian Research and Development Foundation
2006-	Ad Hoc reviewer, NIH Special Study Section on Viral and Eukaryotic Special Emphasis Panel
2007-	Editorial Board of Virology

B. Selected peer-reviewed publications (in chronological order)

Peer-reviewed Publications

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- 10. Bernard, K.A., Maffei, J.G., Jones, S.A., Kauffman, E.B., Ebel, G.D., Dupuis II, A.P., Ngo, K.A., Nicholas, D.C., Young, D.M., **Shi, P.-Y.**, Eidson, M., White, D.J., Stone, W.B., and Kramer, L.D. 2001. Comparison of West Nile virus infection in birds and mosquitoes in New York State in 2000. *Emerg. Infect. Dis.* 7, 679-685.
- 11. G.D., Ebel, Dupuis II, A.P., Ngo, K.A., Nicholas, D.C., Kauffman, E.B., Jones, S.A., Young, D.M., Maffei, J.G., **Shi, P.-Y.**, Bernard, K.A., and Kramer, L.D. 2001. Partial genetic characterization of WNV strains isolated in New York State during the 2000 transmission season. *Emerg. Infect. Dis.* 7, 650-653.
- 12. **Shi, P.-Y.**, Kauffman, E.B., Ren, R., Felton, A., Tai, J.H., Dupuis II, A.P., Jones, S.A., Ngo, K.A., Nicholas, D.C., Maffei, J., Ebel, G.D., Bernard, K.A., and Kramer, L.D. 2001. High throughput detection of West Nile virus RNA. *J. Clin. Microbiol.* 39, 1264-1271.
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Principal Investigator/Program Director (Last, First, Middle): Shi, Pei-Yong

C. Research Support

Contract N01-AI-25490

09/30/02-09/29/09

NIH/NIAID

PI: Laura Kramer Role: Co-Investigator

West Nile and Pox viruses: ecology, pathogenesis and immunology

This is a multi-investigator contract to study the ecology, pathogenesis, and immunology of West Nile and Pox viruses. The scope of this contract includes development of more sophisticated diagnosis, studies of viral transmission cycle, viral pathogenesis, and immunology.

U01 AI061193-01

06/01/04-05/31/09

NIH/NIAID Role: PI

Identifying Inhibitors of West Nile and Dengue Viruses

This grant is focused on identifying novel inhibitors against West Nile and dengue virus replication through high-throughput screening of compound libraries.

1R43AI065156-01

05/01/05-03/31/07

NIH/NIAID

PI: Patrick Iversen (AVI BioPharma Inc.)

Role: Co-Investigator

Antisense Antiviral Agents for West Nile Virus Infection

This is a SBIR grant to develop antisense agents of West Nile virus infection and to study the mechanism of action of the inhibitors.

1 R21 AI065562-01

07/01/05-06/30/07

NIH/NIAID Role: PI

West Nile virus life cycle in flavivirus-resistant cells

This grant is proposed to characterize the molecular mechanism of flavivirus resistance.